

Agenda Item Ie

Proposed legislation
on nonresident
pharmacies

§ 4126.5. Persons or organizations that pharmacies may furnish with dangerous drugs; violations; offset of amounts due; definitions

- (a) A pharmacy may furnish dangerous drugs only to the following, and only the following may receive dangerous drugs furnished by a pharmacy:
- (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
 - (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
 - (3) A licensed wholesaler acting as a reverse distributor.
 - (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
 - (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
 - (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
 - (7) To another pharmacy under common control.
- (b) Notwithstanding any other provision of law, a violation of this section ~~by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities~~ may subject the ~~person or~~ persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.
- (c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under [Section 12419.5 of the Government Code](#). Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.
- (d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.
- (e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in [Section 1418 of the Health and Safety Code](#).

Agenda Item II

- Draft language for e-pedigree regulations on:
 - a) Certification
 - b) Inference
 - c) Inspection
- Comment on background information for Drop Shipments
- Drop Shipment Solicitation for comments

Certification

(a) For the purposes of Business and Professions Code section 4034, and the delivery and receipt of electronic pedigrees, “certification” shall refer to the process by which each participant in the supply chain confirms and attests to the accuracy of electronic pedigrees transmitted or received in conjunction with delivery, transfer, receipt, or acceptance of corresponding dangerous drugs.

(b) Prior to or contemporaneous with any delivery or other transfer of a dangerous drug pursuant to a transaction requiring transmission and receipt of an electronic pedigree, the delivering or transferring party (hereinafter, the “source”) shall transmit to the buying, receiving, or accepting party (hereinafter, the “recipient”) via a secured electronic transmission, the electronic pedigree corresponding to the dangerous drug being delivered or transferred, including every change of ownership of the dangerous drug from its initial manufacture through to the transaction between source and recipient, tracked at the smallest package or immediate container as defined in section 4034, subdivision (d). The electronic pedigree transmitted by the source to the recipient shall include, as to each such individual unit, at least the following:

- (1) The name and principal address of the source, and the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient. If more than one registration or license held by the source would permit the transfer, then the source may elect to include one or more than one of the eligible numbers.
- (2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if the sales invoice number is not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.
- (3) For each owner of the dangerous drug prior to and including the source and the recipient, the business name, address, and federal or state registration and/or license number(s) permitting sale or transfer, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.
- (4) A certification under penalty of perjury from a responsible party of the source that the information contained in the pedigree is true and accurate.
- (5) The unique identification number affixed to the smallest package or immediate container.

The electronic pedigree provided by the source to the recipient shall include a digital signature by a responsible party for the source that prevents any alteration, tampering, or other change to the pedigree, and that guarantees that the data is immutable and non-repudiable by the source.

The certification under penalty of perjury by a responsible party for the source shall attest that, to the best of the ability of the responsible party to know or determine, the information contained in the pedigree is true and accurate. By so attesting, the responsible party confirms that the source has verified the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, that there is nothing in the prior transaction history that raises suspicion, and that the information in the pedigree corresponds to the dangerous drug being transferred.

(c) Prior to or contemporaneous with receiving a delivery or other transfer of a dangerous drug pursuant to a transaction requiring the transmission and receipt of an electronic pedigree, the recipient shall receive an electronic pedigree from the source that corresponds to the dangerous drug being delivered or transferred. The recipient shall certify receipt of the dangerous drug by verifying the prior transaction history and corresponding certifications for the dangerous drug to the best of its ability, confirming there is nothing in the transaction history that raises suspicion, verifying correspondence between the pedigree data and the dangerous drug received, and by including in the pedigree a digital signature by a responsible party for the recipient that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the recipient.

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Inference

(a) Pursuant to Business and Professions Code sections 4034 and 4163.3, participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, shall distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, except where the board by regulation defines circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit. This regulation defines the limited circumstances under which such an inference will be acceptable.

(b) For the purposes of this section, to “infer” or to rely on an “inference” means that a supply chain participant, in reliance on electronic pedigree information received from a trusted trading partner which provides hierarchical relationships between those unique identifiers affixed to the smallest packages or immediate containers and those unique identifiers affixed to the aggregate container (a case or pallet) into which the smallest packages or immediate containers are placed for purposes of distribution, substitutes scan or review of the unique identifier affixed to the aggregate container for a scan or review of the unique identifiers affixed to the smallest packages or immediate containers contained therein, for purposes of certifying delivery or receipt. The supply chain participant then “infers” that the smallest packages or immediate containers within the aggregate container are what they are expected to be, based on the hierarchical pedigree information, and pairs expected shipments and receipts with the actual physical individual units without opening the sealed aggregate container and scanning or reviewing its contents.

(c) Recipients in the supply chain may infer the smallest package or immediate container contents of a sealed case bearing the original, unbroken, seal or tape affixed by the manufacturer, without breaking the seal, thereby relying on the unique identifier affixed to the sealed case and the inference that hierarchical data relationships between the case identifier and the individual unit identifiers as stated in the electronic pedigree have been correctly stated and remain true, and accurately describe the case contents, only under the following circumstances:

- (1) Where the source has transmitted to the recipient prior to receipt of the sealed case a certified electronic pedigree record establishing a hierarchical data relationship between the unique identifier affixed to the sealed case and the individual unit identifiers;
- (2) Where the electronic pedigree data was received via a secured electronic transmission, and includes a digital signature by a responsible party for the source that prevents any alteration, tampering, or other change to the pedigree and that guarantees that the data is immutable and non-repudiable by the source;
- (3) Where the case is and has remained sealed with the original, unbroken, seal or tape affixed by the manufacturer, and shows no signs of tampering or being opened;
- (4) Where the sealed case is homogenous, i.e., contains only one dangerous drug product, and contains no more than forty-eight (48) units of that dangerous drug product;

- (5) Where the sealed case and accompanying pedigree data were received from a trusted trading partner. For the purposes of this section, a “trusted trading partner” is a source:
- a. with which the recipient has an established relationship and existing contract;
 - b. for which the recipient has verified the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient;
 - c. with which the recipient has established agreed and mutually-executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain “trusted trading partner” status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered;
 - d. from which the recipient has received at least five (5) shipments of sealed cases containing homogenous products, has physically verified the individual unit contents, and certified 100% accuracy of the electronic pedigree data received – detailed records of this verification process and the results of the inspections shall be kept and made available for inspection upon request by an authorized officer of the law or by an authorized representative of the board;
 - e. for which there has been no prior need for manual intervention with regard to any sealed cases previously received, other than individual unit identifier scans;
 - f. for which there is written approval by the recipient’s compliance manager, signed under penalty of perjury and maintained for review by the board for as long as the status persists, of “trusted trading partner” status for the source; and
 - g. with which there is a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received;
- (6) Where the source and recipient have agreed and mutually-executed standard operating procedures (SOPs) that define, at minimum, the requirements to gain and maintain “trusted trading partner” status, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered, and where the source and recipient have a written agreement in place specifying the means and time limits of remediation of, and the apportionment of liability for, any discrepancies discovered in either the electronic pedigree data or the drug products received, either or both of which shall be made immediately available for inspection by an authorized officer of the law or by an authorized representative of the board, upon request;

ADDITIONAL CONCEPTS:

- (A) Sampling/audits must be at least at the level of ANSI/ASQZ1.4-2008, Special Level S-1 and the single sampling plan for normal inspections;
- (B) When sealed case is opened, its entire contents must be immediately scanned;
- (C) Any discrepancies discovered in data or products must be remedied within 48 hours;
- (D) The pedigree data must indicate that an inference was deployed for the certifications;
- (E) Liability must be shared by all parties propagating or relying on the inference.

Inspection

- (a) Pursuant to Business and Professions Code sections 4081 and 4105, electronic pedigree records are among the records of manufacture, sale, acquisition, or disposition of dangerous drugs that shall be at all times during business hours open to inspection by authorized officers of the law, that shall be preserved for at least three years from the date of making, and that shall be at all times retained on the licensed premises in a readily retrievable form.
- (b) Electronic pedigree records shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of the electronic pedigree records.
- (c) Upon request by an authorized officer of the law or by an authorized representative of the board, the electronic records shall be made immediately available in electronic format for duplication or download, duplicated or printed into a paper format, or both, as directed.
- (d) Each licensed premises shall have available a scanner and terminal that may be used by an authorized officer of the law or by an authorized representative of the board to access electronic pedigree record information regarding the smallest package or immediate container for any dangerous drug by, among other things, scanning the unique identification number affixed to the smallest package or immediate container and accessing the corresponding pedigree.

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March 14, 2013

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VIA E-MAIL AND U.S. MAIL

Ms. Virginia Herold
California Board of Pharmacy
1625 North Market Street, Suite N219
Sacramento, CA 95834

**Re: Submission of Information Necessary for Board Rulemaking on “Drop Shipment”
and Certification of Individual Package Units Drug Pedigree Law**

Dear Ms. Herold:

On behalf of one of our pharmaceutical manufacturing clients, the purpose of this letter is to submit general information and background on their “direct ship” model, and a draft regulatory template for your consideration. We are pleased to see that the California Board of Pharmacy’s (the “Board”) Enforcement Committee will be undertaking the review of information necessary to initiate future regulatory proceedings on this topic, as authorized by Section 4163.1 of the California Business and Professions Code. Our client, respectfully, wishes to provide regulatory language for Board consideration, stakeholder reaction, and, ultimately, formal rulemaking proceedings that address a very unique business model in the prescription drug distribution supply chain.

As detailed in Exhibits “A” and “B,” below, our client utilizes a “drop-ship” distribution model that provides treating physicians and their patients with timely and efficient access to patients with certain critical, and treatment time-sensitive disease states. Our client has been using the “drop-ship” model for a period approaching a decade, and knows that other companies have used comparable models for greater and shorter periods of time. This model allows our client to facilitate the direct shipment of medications to a healthcare provider’s office, and ultimately to the patient, within a day of placing an order.

In this model, wholesalers place orders for the product and consequently take title to the ordered product, but never take possession or physical control of the product. The role of the wholesaler in this model is thus limited to facilitating product distribution by providing administrative services, such as the processing of orders and payments.

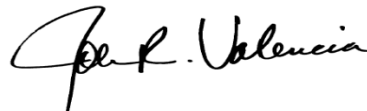
Ms. Virginia Herold
California Board of Pharmacy
March 14, 2013
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Section 4163.1(b) of the California Business and Professions Code permits the Board to establish an alternative process to convey the pedigree information for drugs that are distributed by drop shipment. The intent of the drug pedigree requirements in California law is to provide the capability to track and trace drug shipments. As a result, only those stakeholders that actually take possession or physical control of the drugs are best positioned to satisfy the objectives of the law's pedigree requirements.

In the context of a drop shipment distribution model, pedigree information ought to include records of any shipments from manufacturers to dispensers, as well as any returns. However, we respectfully submit that the pedigree requirements should not apply to wholesale distributors who take only legal title of the drug product but do not take possession or physical control. Ensuring that entities that never physically handle the product are not subject to the reporting requirements will allow companies, such as our client, to maintain important efficiencies in its distribution system, without subjecting its wholesalers to unnecessary regulation, while continuing to provide accurate tracking of pharmaceutical products throughout the chain of physical custody. Recent federal legislative efforts in this area also recognized this distinction between a "drop-ship" model and more traditional distribution models.

Thank you for your consideration in this regard. As you may require any additional information, please don't hesitate to contact me at (916) 441-2430.

Respectfully submitted,

A handwritten signature in black ink, reading "John R. Valencia". The signature is fluid and cursive, with the first name "John" and last name "Valencia" clearly legible.

JOHN R. VALENCIA

JRV:mab

Enclosures: Exhibits "A" & "B"

Exhibit “A”

“Drop-ship” Distribution Process

Some manufacturers use a “drop-ship” distribution model that provides treating physicians and their patients with timely and efficient access to drugs. By using a drop-ship model, the manufacturer can facilitate a direct shipment of its drug to a healthcare provider’s office. In this model, wholesalers place orders with the manufacturer or a designated distributor for the product and consequently take title to the ordered product, but never take possession or physical control of the product. Instead, the manufacturer or designated distributor ships directly to the physician upon receipt of the order. The role of the wholesaler in this model is thus limited to facilitating drug distribution by providing administrative services, such as the processing of orders and payments.

Section 4163.1(b) of the California Business and Professions Code (BPC) permits the California Board of Pharmacy to establish an alternative process to convey the pedigree information for drugs that are distributed by drop shipment. The intent of the drug pedigree requirements in the California BPC is to provide the capability to track and trace drug shipments. Manufacturers are the first step in the pedigree chain. Pedigree information should be passed from each entity who takes physical possession onto the next physical owner within the drug distribution system. In the context of the drop shipment distribution model described above, pedigree information ought to include records of any shipments from manufacturers to dispensers, as well as any returns. However, the pedigree requirements should not apply to wholesale distributors who take legal title of the drug product but do not take possession or physical control. The recent federal legislative efforts in this area also recognized this distinction between a “drop-ship” model and a more traditional distribution model.

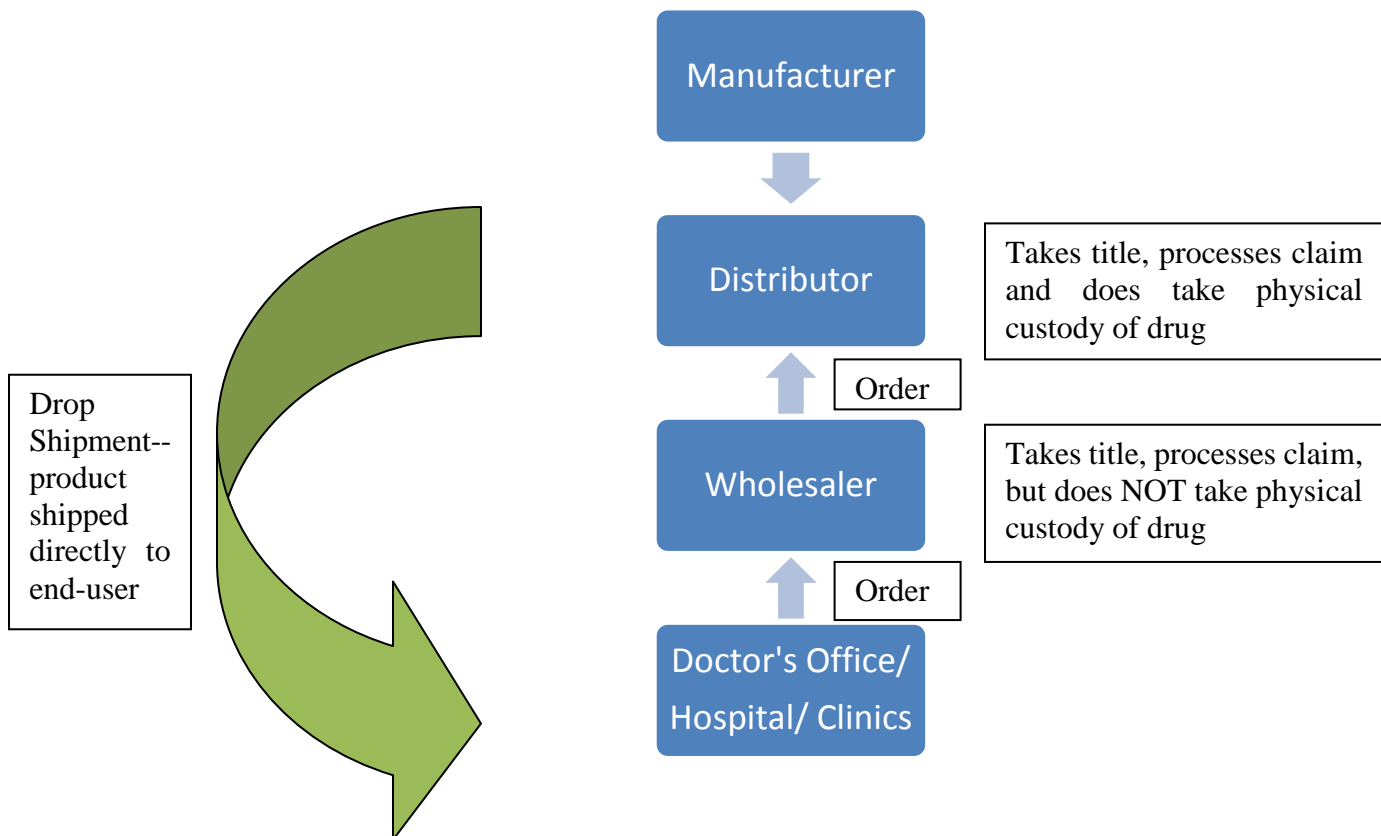
Any potential regulations should ensure that entities who never physically handle the product are not subject to the reporting requirements. This will allow manufacturers to maintain important efficiencies in their distribution system, without subjecting the wholesaler to unnecessary regulation, while continuing to provide accurate tracking of pharmaceutical products throughout the chain of physical custody. The “drop-ship” model also significantly benefits patients by allowing for quicker access to treatments via a just in time delivery system-often the drug is delivered within 24 hours of placing an order. This model obviates the need for physicians to keep a large stockpile of drugs in their inventory, thus ensuring patients have safe and quicker access to life extending drugs. The following draft language is submitted for your consideration as you develop regulations to implement the law.

Proposed Draft: Limitation on Reach of Drug E-Pedigree Requirements in the Instance of “Drop Shipment” Sales of Dangerous Drug Products in California (Authority: Bus. & Prof. Code Sec. 4163.1)

“_____. For the purposes of Business and Professions Code Section 4163.1, when a manufacturer utilizes the “drop shipment” means of sale for a dangerous drug product as defined by that section, only those entities involved in the physical handling, distribution, or storage of a dangerous drug product, are required to provide or receive the “pedigree” required by Section 4034. Any entity, including but not limited to a wholesale distributor, that is not involved in the physical handling, distribution, or storage of the dangerous drug product sold by means of “drop shipment,” is not required to provide or receive a pedigree for that dangerous drug product, [even if such entity holds legal title to the dangerous drug product]. For purposes of this section, facilitating the distribution of a product by providing various administrative services, including processing of orders and payments, [even if holding title,] shall not, by itself, be construed as being involved in the physical handling, distribution, or storage of a product.”

Exhibit "B"

A 'DROP-SHIP' DISTRIBUTION MODEL





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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: All Interested Parties

Subject: Opportunity to Submit Information Necessary to Possible Board Rulemaking

On "Drop Shipment" and Certification of Individual Package Units
Drug Pedigree Law

Pursuant to Business and Professions Code section 4163.1 (see below), the Board of Pharmacy is confirming its willingness to receive information by written submission regarding supply chain participants' ability to use or rely on drop shipment(s) as an effective alternative process to convey the pedigree information for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law. (Bus. & Prof. Code, § 4034, 4163 et seq.)

To be considered for purposes of developing a possible future Board rulemaking on this subject, we request that all written submissions contain at minimum the information outlined below, and be received by mail or personal delivery at the Board offices by no later than March 12, 2013.

- "4163.1.(a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:*
- (1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.*
 - (2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.*
 - (3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.*
- (b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment."*

Section 4163.1 specifies parameters within which the "drop shipment" conveyance of dangerous drugs by a manufacturer must comport in order to qualify as an alternative process for pedigree information transfer. The Board must relate any regulation establishing "drop shipment" as an alternative process for conveyance of pedigree information on the factors contained in the statute. Accordingly, the Board would benefit from supply chain members' input as to business circumstances utilizing the "drop shipment" model in order to craft and/or issue regulations under which it would be permissible as an alternative process as set forth in statute.

This notification confirms that the Board will accept written submissions from interested parties, in support of or in opposition to permitting drop shipment under specified circumstances, to develop the record necessary to any Board rulemaking on the subject of drop shipment and/or certification.^{[\[1\]](#)}

Necessary Information in Submissions

Any submission by an interested party should include at least the following:

1. Identifying and contact information for the submitting person or entity.
2. A description of the submitting party's interest in this subject, including the submitting party's role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.
3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy that satisfactorily establishes the drop shipment model as an "alternative process for conveyance of pedigree information."
4. If the submitting party is seeking a regulatory allowance for drop shipment, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived or actual need for regulations to accommodate the drop shipment model. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which drop shipment might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the drop shipment process.
5. If the submitting party is opposed to a regulatory allowance for drop shipment, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.
6. The detailed reason(s) that drop shipment is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting or other risk(s) in the supply chain, holds risk(s) constant, or does not unacceptably increase such risk(s).
7. A schematic diagram to illustrate how the drop shipment works with respect to how the product moves and how the ownership transfers.

Where and When to Submit

All written submissions should be mailed or delivered to Executive Officer Virginia Herold, Board of Pharmacy, 1625 N. Market Blvd., Suite N219, Sacramento, CA 95834. Materials received on or before 12:00 Noon, Tuesday, March 12, 2013, will be considered by the Board in developing a possible rulemaking. These submissions will be considered at the Enforcement Committee meeting on March 14, 2013, and/or at the full Board meeting on April 24-25, 2013.

^[1] The Board expects that submissions will be made primarily by individual persons, companies, or other entities that are themselves involved in the supply chain and able to supply information and data specific to their own operations regarding the potential benefits and risks of drop shipment. Although the Board also welcomes input from associations and other groups, it is most interested in the kind of detail that individual submissions can better provide. The Board is also interested in hearing from vendors, consultants, standards bodies, hardware and software providers, and other experts in the field, regarding their viewpoints on and experience(s) with the use of drop shipment.